This report is required by law (7 USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject lo penalties as provided for in Section 2150

See reverse side for additional information.

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Interagency Report Control No 0180-DOA-AN
BY:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY *(TYPE OR PRINT)*

1. REGISTRATION NO. 13-R-0001 **CUSTOMER NUMBER** 273

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)

University of Vermont
State Agricultural College
116 Hills Building
Burlington, VT 05405

Telephone: (802) 656-0459

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(sites)*

(b)(2)High, (b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress. or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs			8		8
5. Cats					
6. Guinea Pigs		327		107	434
7. Hamsters					
8. Rabbits		100	10		110
9. Non-human Primates					
10. Sheep					
11., Pigs			93		93
12. Other Farm Animals					
13 Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached lo this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6),(b)(7)(c)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*

(b)(6),(b)(7)(c)

DATE SIGNED 11/06/2006

PART 1 - HEADQUARTERS

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are required as part of an explanation. A column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: Customer # 273, Certificate # 13 – R- 0001

2. Number 107 of animals used in this study.

3. Species (common name) Guinea pigs of animals used in this study.

4. **Explain the procedure producing pain and/or distress.** The purpose of this study is to study the interactions between the nervous system and the immune system that occur with inflammatory bowel disease. Inflammatory bowel disease is a chronic inflammatory disorder of the colon in humans characterized by diarrhea and severe abdominal pain. This study utilizes a guinea pig model for *in vitro* experiments involving analysis of intact layers of the colon. Alterations in colon reflex nerve pathways during inflammation and the responses of colon neurons are studied. The study is designed to establish what changes occur in neuronal circuitry in the colon during inflammation. The inflammation is produced by injecting 0.5 ml of the chemical agent trinitrobenzene sulphonic acid (TNBS) under anesthesia into the lumen of the guinea pig's colon by enema. The animals recover from anesthesia and undergo three days of suppressed food intake. Feeding frequency is not altered, only amount consumed. Animals are observed twice daily for five days followed by once daily for an additional five days. They are weighed daily post-TNBS until they have gained weight three days in a row. Any guinea pig losing >20% of body weight in a three-day period post-TNBS is euthanized. The guinea pigs also receive cyclooxygenase (COX 2) inhibitor subcutaneously to block prostaglandin formation and eliminate the protective effect of prostaglandins on the intestinal mucosa. With the described procedures, the guinea pigs develop mild inflammatory bowel disease, then recover and resume weight gains. The animals are euthanized over the next 3-56 days. Since these animals are developing inflammatory bowel disease which is painful in people, the UVM IACUC has insisted that this animal model be classified as an E level protocol. The approved IACUC protocol numbers are 07-007 and 07-008.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods used to determine that pain and/or distress relief would interfere with test results.** The UVM IACUC insisted on the use of an analgesic agent when this model was first proposed and attempted at the University of Vermont. The analgesic agent buprenorphine decreased intestinal motility in this model resulting in increased TNBS residence time in the colon. Perforation of the colon occurred with secondary peritonitis and death of all six animals on the initial experiment. No useful research data were collected on inflammatory bowel disease from these animals. All six had evidence of TNBS in the peritoneal cavity. After observing the transient nature of the disease, the veterinarians recommended that the model be allowed without analgesic drug use, and that the protocol be classified as an E level protocol so that the study could proceed.

6. **What federal regulations require this procedure?** Not Applicable.

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BY:

The University of Vermont

UNIVERSITY VETERINARIAN
OFFICE OF ANIMAL CARE MANAGEMENT
116 HILLS AGRICULTURE SCIENCE
BURLINGTON, VT 05405-0082
TEL. (802) 656-0459
FAX: (802) 656-8315

November 3, 2006

Dr. Elizabeth Goldentyer
Regional Director – Animal Care
USDA APHIS
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Dear Dr. Goldentyer,

Please find enclosed the University of Vermont's Annual Report (APHIS form 7023) and [illegible]
E explanation. Could you please acknowledge receipt of this report by email (b)(6),(b)(7)(c)

Many thanks,

(b)(6),(b)(7)(c)

Enc. (2)

Xc: (b)(6),(b)(7)(c)